

II. REMARKS


Applicants have amended the claims for clarity. Accordingly, no new matter has been added.

III. SUMMARY

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 490042800000. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

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Version with markings to show changes made

1. (Amended) A method for [producing] isolating hemoglobin [solution] from a solution containing red blood cells within a[n automated blood separator comprising a centrifuge] container, the method comprising the steps of:

(a) [isolating] separating the red blood cells [in] from the solution:

(b) [removing the supernatant produced during the step of isolating;]

washing the red blood cells in a wash solution;

(c) lysing the red blood cells to produce stromata and a hemolysate containing hemoglobin having an ionic strength, wherein said lysing step further comprises measuring the ionic strength of the hemolysate formed by exposing the red blood cells to a hypotonic solution; and

(d) separating the hemolysate from the stromata [of the red blood cells from the hemolysate.];

wherein steps (c) and (d) are simultaneously carried out or sequentially repeated until the ionic strength of the hemolysate is below a predetermined level.

2. (Amended) The method of claim 1, wherein the wash solution further comprises a normal saline solution.

3. (Amended) The method of claim 1, wherein the wash solution further comprises an agent for killing bacteria.

4. (Amended) The method of claim 1, wherein the wash solution further comprises an agent to remove or inactivate [viruses] organisms.

5. (Amended) The method of claim 1, wherein steps (a) through (d) are performed within a single processing container [disposed within the centrifuge].

7. (Amended) A method performed within a cell processing apparatus for [producing] isolating hemoglobin from a solution containing red blood cells and plasma, the method comprising the steps of:

collecting the solution in a sterile processing set comprising a processing bag and a tube harness, wherein the processing bag is disposed within a centrifuge in the cell processing apparatus;

separating the red blood cells from the plasma by rotating the processing bag within the centrifuge;

expressing the plasma from the processing bag;

introducing a washing solution into the processing bag to wash the red blood cells;

expressing the supernatant after washing;

lysing the red blood cells [by introducing distilled water into the processing bag to liberate hemoglobin in solution] to produce stromata and a hemolysate containing hemoglobin having an ionic strength, wherein said lysing step further comprises exposing the red blood cells to a hypotonic solution;

separating [red blood cell membranes from the hemoglobin solution] the hemolysate from the stromata by rotating the processing bag in the centrifuge; and

removing the [hemoglobin solution] hemolysate through a sterile port in the processing bag.

8. (Amended) The method of claim 7, wherein the step of separating [red blood cell membranes from hemoglobin] the hemolysate from the stromata further comprises the steps of:

removing [the first-produced hemoglobin] the hemolysate produced when the [distilled water] hypotonic solution initially contacts the red blood cells; and

continually removing additional [hemoglobin] hemolysate produced as [an] the ionic strength of the [solution] hemolysate decreases.

9. (Amended) The method of claim 8, further comprising the steps of:

measuring the ionic strength of [a hemoglobin solution produced by the step of removing the hemoglobin from the solution] the hemolysate;

adding additional [distilled water] hypotonic solution; and
simultaneously carrying out or repeating the steps of [removing the additional
hemoglobin and addition the additional distilled water] adding additional hypotonic solution and
removing hemolysate until the ionic strength [reaches] is below a predetermined [threshold]
level.

10. (Amended) A method [of separating] for isolating hemoglobin from [packed] a
solution containing red blood cells within a processing container in a cell processing apparatus,
the method comprising the steps [performed within the apparatus] of:

washing the red blood cells in the processing container with a saline solution;

lysing the red blood cells in the processing container to produce stromata and a
hemolysate containing hemoglobin having an ionic strength, wherein said lysing step further
comprises measuring the ionic strength of the hemolysate formed by exposing the red blood
cells to a hypotonic solution; and

separating [red blood cell membranes and unlysed red blood cells from
hemoglobin] the hemolysate from the stromata and red blood cells within the processing
container; and

extracting the [hemoglobin in solution] hemolysate from the processing
container[.];

wherein the steps of lysing and separating are simultaneously carried out or sequentially
repeated until the ionic strength of the hemolysate is below a predetermined level.

11. (Amended) The method of claim 10, wherein the step of separating further
comprises centrifuging the processing container within the apparatus to pack the [red blood cell
membranes] stromata and [unlysed] red blood cells.

12. (Amended) The method of claim 10, wherein the step of washing [includes]
further comprises adding a detergent, antibacterial or antiviral agent to the saline solution.

14. (Amended) A method for preparing a modified hemoglobin solution comprising the steps of:

mixing [packed] red blood cells [into a] with [normal] saline solution;

[washing the red blood cells with a saline solution;]

lysing the red blood cells to produce stromata and a hemolysate containing hemoglobin having an ionic strength, wherein said lysing step further comprises exposing the red blood cells to a hypotonic solution;

[diafiltering the red blood cells to remove the stromata;]

[diafiltering the filtered red blood cells;]

separating the hemolysate from the stromata; and

[collecting] mixing the [resulting hemoglobin solution] hemolysate [into a container, wherein the container contains premeasured reagents adapted for chemical modification of the hemoglobin solution;] with a reagent adapted to chemically modify the hemoglobin to form a chemically modified hemoglobin solution

[reacting the hemoglobin solution with the reagents; and

storing the reacted solution in a storage container].

16. (Amended) The method of claim [15] 14, wherein the [buffer salts are iminothiolane and] reagent comprises activated polyethylene glycol.

17. (Amended) The method of claim 14, further comprising filtering the [reacted solution] chemically modified hemoglobin solution.

18. (Amended) The method of claim 14, further comprising sterilizing the [reacted solution] chemically modified hemoglobin solution [to remove or inactivate organisms].